



Food and Drug Administration  
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Silver Spring, MD 20993-0002

January 13, 2015

Intelligent Implant Systems, LLC  
Mr. Michael Nutt  
Chief Operating Officer  
3300 International Airport Drive, Suite 1100  
Charlotte, North Carolina 28208

Re: K142939

Trade/Device Name: Revolution™ Spinal Fixation System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class III  
Product Code: NKB, MNI, MNH  
Dated: December 15, 2014  
Received: December 16, 2014

Dear Mr. Nutt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Lori A. Wiggins -S**

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known): K142939

Device Name: Revolution™ Spinal Fixation System

### Indications for Use:

The Revolution™ Spinal Fixation System is intended for pedicle screw fixation of the non-cervical posterior spine in order to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) spondylolisthesis, (3) trauma (i.e., fracture or dislocation), (4) spinal stenosis, (5) deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), (6) tumor, (7) pseudoarthrosis, (8) failed previous fusion.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**510(k) SUMMARY****Intelligent Implant Systems' Revolution™ Spinal Fixation System**

**I. Submitter:** Intelligent Implant Systems, LLC  
3300 International Airport Drive, Suite 1100  
Charlotte, NC 28208  
(704) 424-1009  
(704) 424-1011 (FAX)

**Contact Person:** Michael Nutt  
Chief Operations Officer  
(704) 424-1009

**Date Prepared:** December 15, 2014

**II. Device**

**Name of Device:** Revolution™ Spinal Fixation System

**Common or Usual Name:** Spinal Fixation System

**Classification Name:** Non-Cervical, Pedicle System (21 CFR 888.3070)

**Regulatory Class:** III

**Product Codes:** MNI, MNH, NKB

**III. Predicate Devices**Primary Predicate:

LifeSpine PILOT®-P Posterior Lumbar Plating System (K061364)

Additional Predicates:

Medtronic Sofamor Danek: Dynalok Classic™ Spinal System (K023415)

Spinal Innovations Ascend with Shadow Spinal Fixation System (K013196)

#### **IV. Device Description**

The Intelligent Implant Systems' Revolution™ Spinal Fixation System consists of monoaxial bone screws of various lengths and diameters and a series of connector assemblies for connecting the bone screws.

The Revolution™ Bone Screws have a standard thread for interfacing bone and a partially threaded post designed to engage the Revolution™ Connectors. Screws are available in 4.5mm major diameter and lengths from 25mm to 50mm and 5.5mm, 6.5mm, and 7.5mm major diameters and lengths from 25mm to 55mm. All screw diameter sizes except for the 4.5mm are cannulated for use with a 1.4 mm k-wire. To allow the surgeon to determine the height of the connector relative to the bone, screws with extended non-threaded collars are provided. These extended collars effectively provide built in spacers that prevent the bone screw from being driven too deep and control the overall height of the completed assembly.

The Revolution™ Connectors are provided in various lengths and are used to connect the pedicle screws and create a rigid structure. To allow for variation in screw placement, each end of the connector allows for angular compensation. One end allows for full polyaxial angulation, similar to a typical polyaxial screw. The other end has a pivoting-slide that allows for angulation in only one plane along the long axis of the Connector while also sliding within an opening in the Connector. As the distance between two screws is always variable, the slide allows the Connector to compensate for this difference, minimizing inventory and eliminating the need to cut spinal rods. In addition, the Connectors have a threaded locking nut built into each end and each nut fits over the top of a bone screw post. These locking nuts are turned clockwise to tighten. A calibrated torque wrench provides the correct setting for locking the nuts on the bone screw post with sufficient force. The system can be unlocked, if necessary, by turning the locking nuts counterclockwise.

All implant components of the Revolution™ Spinal Fixation System are manufactured from Ti-6Al-4V ELI alloy, conforming to ASTM F136.

#### **V. Indications for Use**

##### **Indications for Use:**

The Revolution™ Spinal Fixation System is intended for pedicle screw fixation of the non-cervical posterior spine in order to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) spondylolisthesis, (3) trauma (i.e., fracture or dislocation), (4) spinal stenosis, (5) deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), (6) tumor, (7) pseudoarthrosis, (8) failed previous fusion.

## **VI. Comparison of Technological Characteristics with the Predicate Devices**

The Revolution™ Spinal Fixation System and the predicate devices are all posterior systems utilizing pedicle fixation for stabilization of spinal segments. At a high level, the subject and predicate devices all have the following technological characteristics:

- Bone thread used to implant bone screws in pedicles
- Lock nuts or bolts used to attach bone screws to plates or rods
- Torque is applied to lock nuts or bolts to secure assemblies

The following technological differences exist between the subject and predicate devices:

- Adjustability is provided in the connector design, not the screw head as seen in rod systems
- Connectors allow more adjustability than predicate plate designs by incorporating a polyaxial connection at one end and a pivoting-slide connection at the other end
- Geometry of the Revolution™ connector is a 5.5 mm rod in the center, with a plate-like construct on the ends

## **VII. Performance Data**

The following performance data were provided in support of the substantial equivalence determination:

### Mechanical Testing:

To validate the strength and safety of the system, testing was conducted according to methods defined in ASTM F 1798-13, “Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants”, and ASTM F 1717-14, “Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model”. The types of testing performed on the polyaxial and sliding screw assemblies are listed below.

### Testing per ASTM F1798-13

The following types of testing were performed on the Revolution™ Spinal Fixation System per ASTM F1798-13:

1. Static Flexion-Extension Strength
2. Axial Gripping Strength
3. Static A-P Pullout Strength

### Testing per ASTM F1717-14

The following types of testing were performed on the Revolution™ Spinal Fixation System per ASTM F1717-14:

1. Static Compression Bending

2. Static Torsional Bending
3. Dynamic Compression Bending

The testing revealed that the mechanical properties of the Revolution™ Spinal Fixation System were comparable to published values on plate and rod systems.

Materials: All components of the Revolution™ Spinal Fixation System are machined from Ti-6Al-4V ELI, conforming to ASTM F-136.

Summary: Based on the mechanical testing that was performed and the composition of the device, the Revolution™ Spinal Fixation System was found to have a safety and effectiveness profile similar to the predicate devices.

### **VIII. Conclusions**

The design of the Revolution™ Spinal Fixation System is similar to the predicate devices, it functions in a similar manner, and its mechanical properties are comparable. Thus, the Revolution™ Spinal Fixation System is substantially equivalent to the predicate devices in design, function, materials, mechanical performance, and intended use.